IX. 510(k) Summary

K041119

JUL 19 2004

SUBMITTER:	DePuy Spine, Inc. 325 Paramount Drive Raynham, MA 02780
CONTACT PERSON:	Jennifer Mooney
DATE PREPARED:	April 26, 2004
CLASSIFICATION NAME:	Appliance, Fixation, Spinal Interlaminal Orthosis, Spinal Pedicle Fixation, Spinal Intervertebral Body Fixation
PROPRIETARY NAME:	Expedium Spine System
PREDICATE DEVICES:	Expedium Spine System (Merlin Spine System) k033901
DEVICE DESCRIPTION:	Expedium Spine System components are designed to accept a 5.5mm rod and are available in various geometries and sizes. The Expedium Spine System also contains Class 1 manual surgical instruments and cases that are considered exempt from premarket notification
INTENDED USE:	The Expedium Spine System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.
MATERIALS:	Manufactured from ASTM F-138 and F-1314 implant grade stainless steel and ASTM F-136 implant grade titanium alloy.
PERFORMANCE DATA:	Performance data were submitted to characterize the additonal Expedium Spine System components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 2004

Ms. Sharon Starowicz
Director, Regulatory Affairs
DePuy Spine, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K041119
Trade/Device Name: Expedium Spine System
Regulation Number: 21 CFR 888.3050; 21 CFR 888.3060; 21 CFR 888.3070
Regulation Name: Spinal interlaminar fixation orthosis, Spinal intervertebral body fixation orthosis, Pedicle screw spinal system
Regulatory Class: II
Product Code: KWP, MNH, MNI, NKB, KWQ
Dated: June 25, 2004
Received: June 28, 2004

Dear Ms. Starowicz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

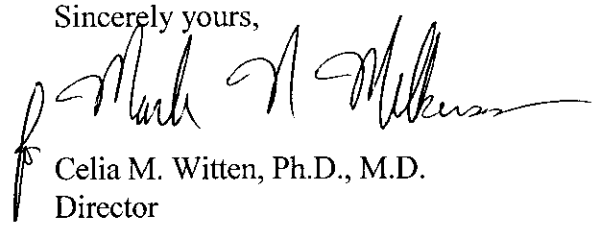
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

III. Indications for Use

510(k) Number (if known): K041119

Device Name: Expedium™ Spine System

Indications For Use:

The Expedium™ Spine System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A. Millerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041119